Draft

ADVISORY COMMITTEE ON MICROBIOLOGICAL SAFETY OF BLOOD AND TISSUES

MINUTES OF 35th MEETING: HELD ON THURSDAY 20 JANUARY 2005

Chair: Professor Lindsey Davies

Members:
Dr Cant
Dr Dash
Dr Mortimer
Dr Robinson
Dr Rudge
Dr Stainsby
Dr Warren
Dr Wyatt

Observers:

Ms Balmer	- MHRA
Dr Bennett	- DH
Mr Connon	- DH
Mr Dobra	- DH
Dr Jones	- WBS
Dr Keel	-SE
Ms Mills	- DH
Ms Norman	- DH
Dr O'Shaughnessy	- DH
Ms Slatter	- WAG
Dr Stephenson	- DH

In attendance:

Dr Galea	- SNBTS, for item 3
Dr Turner	- SNBTS, for item 3
Mr Cayton	- DH, for item 4
Ms Lawrence	- DH, for item 4
Dr Barlow	- for item 4
Dr Hewitt	- NBS, for item 5
Dr Soldan	- HPA, for item 6

Secretariat: Dr Jecock

Introduction and apologies

1. The Chair welcomed members and observers to the meeting. Dr Rudge, Medical Director of UK Transplant, had been invited to join MSBT. As NBS and UK Transplant were preparing to merge later in 2005, and as there was no separate Department of Health mechanism for assessing the microbiological safety of transplanted organs, it was proposed that MSBT should encompass this role. The Chair would

seek the Chief Medical Officer's agreement that the Committee should be in future include this in its remit, and it would therefore be appropriate for it to be known as the Committee on Microbiological Safety of Blood, Tissues and Organs (MSBTO).

2. Mr Gutowski (previously Head of Blood Policy at DH) had moved to a new job on promotion in December. The Chair would write to him on behalf of the Committee, to thank him for his very valuable work for MSBT.

Agenda Item 1: Minutes of the meeting held on 12 October 2004

3. The minutes were accepted.

Agenda Item 2: Matters arising

4. Actions arising from the minutes were reported as either having been completed or on the agenda for this meeting. Brief feedback was reported on the following actions:

5. Action 34(5): A draft note has been prepared for Ministers.

6. Action 34(6): The blood services were content to provide annual updates to the Committee on the impact of new activities.

7. Action 34(7): This action is in train.

8. Action 34(8): The Committee was told that the European Blood Alliance was concerned about emerging infections, and was establishing a group to consider this issue in detail.

9. The Committee was made aware that that NBS considered that the target of harvesting 50% of platelets by apheresis by December 2005 would be difficult to achieve. (Reported in paragraph 30).

Agenda Item 3: Report back from MSBTO Sub-group on Bone & Tissue

10. The Chair welcomed Dr Turner and Dr Galea. Dr Turner presented a report on the recommendations from the sub-group meeting of 10 January (summarised in Dr Turner's letter to Professor Davies of 12 January (appendix 1 of the meeting papers)).

11. Proposal to implement cadaveric vCJD testing. The sub-group supported the principle of vCJD testing for cadaveric multi-organ and tissue donors, but highlighted a number of issues that would need to be addressed, or were already being considered by NBS Tissue Services. The sub-group recommended:

- that NBS should proceed with their plans for testing tonsil/spleen;
- early involvement of UK Transplant, in order to consider how a positive result could be managed in a situation where organs had already been transplanted;

- pilot work would be needed to establish how testing might be implemented for eye-only donors, and to validate testing of optic nerve/neuro-retina.

12. Members agreed that there is a risk that vCJD infection could be amplified via transplantation where organs or multiple tissues are transplanted from one donor, and that if testing is feasible, there would need to be strong arguments for not doing so. In conclusion, the Committee was in favour of cadaveric vCJD testing for tissue donors, but agreed with the sub-group that considerable work was needed to address a number of practical and ethical issues. A pilot testing facility would be sensible in the first instance to address some of these issues. The Committee also asked for further consideration to be given to the applicability of testing of multi-organ donors.

    Action 35(1):Dr Rudge to discuss the applicability of testing multi-organ donors with colleagues from organ transplant community.

    Action 35(2):The Bone and Tissue Sub-group to further advise on the practical issues, seeking advice from other professional groups as necessary.

13. Tissue processing. The Committee concurred with the sub-group's view that there did not appear to be a convincing argument for undertaking CD34 enrichment prior to haematopoietic stem cell transplantation.

    Action35(3): Dr Turner to consult further with **Dr Cant** and to write to medical colleagues accordingly.

14. The Committee approved the intention to discuss bone processing with the orthopaedic surgeons, in order to clarify the current position on possible vCJD risk associated with donated bone, and the relative merits and risks of unprocessed versus processed bone.

    Action 35(4): Dr Galea to covene a meeting with orthopaedic surgeons

    Previously minuted

15. Donor exclusion. For femoral head donation, members noted the Sub-Group's view that proposed deferral of live donors was likely to have a significant impact on supply in England/Wales, although a lesser impact in Scotland. It was noted that two independent banks in England had implemented this exclusion policy and had managed to compensate for loss of supply. It was also noted that there would at this time be some scope to partially replace live donations from cadaveric supply, but that if a blanket exclusion policy were implemented (exclusion of all previously –transfused donors), it would more or less eliminate cadaveric bone donation. Members were concerned that if implementation resulted in a serious supply shortage, one risk might be inadvertently substituted by another. It was therefore

recommended that exclusion of live donors of femoral heads who had previously been transfused should be implemented prospectively, although where records exist, and where it is practicable to do so, retrospective exclusion could be undertaken. MSBT would await advice from SEAC on whether there might be any scientific basis to enable a distinction to be made between historical transfusion and peri-mortem transfusion, before making further recommendations.

Action 35(5): Secretariat to draft a letter, setting out this advice for members' comment

Action 35(6): The Bone and Tissue Sub-group will advise further on the issue of peri-mortem transfusion once advice is received from SEAC.

16. The advice to exclude previously-transfused live donors of bone would not currently be extended to live donors of other tissues or organs. The Committee agreed that in cases where a transplant is potentially life-saving, the balance of risk may be different. There was discussion of the possibility of excluding use of cord blood from previously-transfused mothers, but it was noted that such transfusions are usually urgent, and cord blood is generally used only when no related donor is available. The Committee requested that the Bone and Tissue Sub-group consult with paediatric haematologists on this issue.

17. Selection by age. There was no discussion of this item, as expert advice was awaited from SEAC.

18. Importation of tissues. Investigation of possible options for import of bone had raised questions both about quality, and security of supply from some sources. Members asked for further exploration of the possibility of importing bone from other sources for paediatric use. Amniotic membrane usage is very low, and members agreed there appeared to be no case for proceeding with importation. With regard to possible importation of ocular tissue, potential problems with safety, quality and supply were identified. Rather than pursuing possible import of ocular tissue, members requested further work to assess the feasibility of age matching donors with recipients born after August 1996.

Action 35(7): The Bone and Tissue Sub-group would undertake further assessment.

19. Alternative substitutes. The Committee heard that two controlled trials are currently underway to compare synthetic bone substitutes. The importance of the trials having sufficient statistical power to give confidence in the outcomes was agreed. Dr Galea would raise this point with orthopaedic specialists involved in the trials.

George — update

Agenda Item 4: Potential for transmission of blood-borne viruses/vCJD from aesthetic filler products

20. The Chair welcomed Mr Cayton, Ms Lawrence and Dr Barlow for this item, which had been raised through an expert group report on cosmetic surgery. The Committee's advice was sought on the possibility that some aesthetic fillers might, in some instances, pose a potential microbiological hazard. Dr Barlow explained the main types of injectable filler available, and how they are used. Some contain animal/bird tissue (primarily collagens), and some are synthetic (some made via recombinant technology). Allogeneic human tissue is also sometimes used as a subcutaneous filler. The Committee heard that safety of these products was believed to be generally good. There were no identified reports of infections arising, although granulomatous reactions were not uncommon with certain types of filler, especially the older agents. Members heard from the Medicines and Healthcare Regulatory Agency (MHRA) that fillers used only for cosmetic purposes do not fall within the definition of either medicines or medical devices, and therefore may not be covered by medicines or devices legislation. A few types of filler are used for certain medical treatments, and are regulated as medical devices. However, medical device regulations specifically exclude human-derived material. MHRA, together with DTI (which has responsibility for regulation of cosmetics), is looking to see what regulatory options may be possible, taking into account existing and proposed EU legislation. The Committee was of the view that there could be a potential infection risk from some aesthetic fillers used in cosmetic surgery, although with the information available to it, it was not possible to identify specific areas of concern. A clear regulatory framework would be desirable, both for the products themselves and those who use them.

Agenda Item 5: vCJD notifications to the UK Blood Services

21. The Chair invited Dr Hewitt to present this item. Currently, each vCJD case for whom the NCJDSU is informed of a transfusion history, is notified only to the blood service for the country of residence of the case. The combined view of the UK blood services is that this may result in a small risk of not identifying a donor who may have given blood to the vCJD case, and that added security would be achieved if all UK blood services were notified of every case. Members agreed this would be a sensible precaution.

Action 35(8): Secretariat to prepare a letter for the Chair to send to the Director of the NCJDSU, requesting that all UK Blood services be notified of each vCJD case for whom a transfusion history is identified.

Agenda Item 6: vCJD reverse risk assessment (assessing the implications for blood donors if transfusion recipients are infected with vCJD)

22. Dr Bennett presented this item to the Committee. All risk assessments undertaken to date in relation to blood transfusion examine the possible consequences for the recipient who may have received a

transfusion from an infected donor. In this case, the assessment examines the possible implications for donors whose blood has been transfused into a patient who later developed vCJD. The Committee heard that the CJD Incidents Panel had also briefly considered the risk assessment at its meeting on 18 January, and intended to consider the public health consequences in detail. Members agreed that it would be important to carefully examine both the potential risk to public health, and the implications for the individual donors, and asked for the opportunity to consider the issues in more depth.

Agenda Item 7: Any other business

23. Three items of AOB were reported. Dr Robinson reported that European directives on blood quality and safety were currently before Parliament. It was expected that the blood directive would become law on 8 February, although the UK has a derogation not to implement until November 2005. MHRA would act as the interim competent authority until the establishment of RAFT.

24. The Chair reported on the Arms Length Body review: the merger between NBS and UK Transplant was progressing. Further advice from MSBT may be required on options relating to the safety of blood and tissues.

25. Mr Connon reported that the expected review of the entire committee structure for blood and tissue safety and quality would begin shortly. Members would be kept informed of progress.

Agenda Item 8: Date of next meeting

The next meeting will be held on 28 June 2005